

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 22-0894V

JASMIN AUGUSTINE, Parent and
Natural Guardian of S.A., a Minor,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: August 15, 2022

PRE-ASSIGNMENT REVIEW (“PAR”) - INITIAL ORDER

This matter has been preliminarily assigned to the Chief Special Master while it goes through the Office of Special Masters’ recently-established PAR process. A description of that process, and the parties’ obligations thereto, hereby follows. In accordance with my directives and explanations below, **Petitioner shall file the certified¹ records pertaining to the claim on or before September 14, 2022. (30 days)**

A. The PAR Process.

The Vaccine Act² includes the statutory requirement that each Petitioner’s initial submissions, including the petition and the supporting documents, will contain the Petitioner’s case-in-chief. Section 11(c) of the Vaccine Act requires that each petition be filed with supporting documentation. Incomplete medical records can result in delays in processing petitions by the Office of Special Masters and Respondent. Accordingly, the objective of PAR is to process petitions more efficiently by ensuring that cases are not assigned to a special master or the Special Processing Unit (“SPU”) until the record is deemed substantially complete and ready for medical review by HHS personnel.

¹ See Vaccine Rule 2(c)(2)(A) and Vaccine Rule 2(f).

² The National Childhood Vaccine Injury Act (“Vaccine Act”), as amended, 42 U.S.C. §§ 300aa-1 to -34, which established the National Vaccine Injury Compensation Program (“the Program”). Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Initially, all newly-filed petitions³ will be assigned to the Chief Special Master's docket. The Office of Special Masters will thereafter complete a review of the case filings to determine if the record is substantially complete as required by Section 11(c) of the Vaccine Act. The initial PAR review will result in either an Activation Order (if the medical records and other evidence are substantially complete) or a PAR Scheduling Order setting forth the remaining filings required to complete the PAR process.⁴ Once activated, the case will be assigned to a special master for its adjudication.

Follow-up scheduling orders will be issued as necessary until substantial completeness of the record is achieved. Due to the large number of petitions that have been filed in 2021, the review of cases after the filing of the Statement of Completion will require additional time. If at the end of 60 days after the Statement of Completion is filed, no Activation Order or PAR Scheduling Order has been issued, Petitioner may move for an assignment of the case.

B. Initial Requirements of PAR Assignment

The deadline to hold an initial status conference in this case is **SUSPENDED** until the PAR process is complete and the Activation and Reassignment Order has been issued. Respondent's deadline for filing the Rule 4(c) report is **SUSPENDED** until further notice. See Vaccine Rule 4(c)(1) (allowing me to determine the timing for Respondent's Rule 4(c) report).

C. Motions for Enlargement of Time.

If Petitioner is unable to meet any deadline set forth in this Initial Order, a motion for enlargement of time pursuant to Vaccine Rule 19(b) must be filed.

PLEASE NOTE: During the PAR process, the requirement of Vaccine Rule 19(b)(3), which requires the moving party to discuss the motion with opposing counsel to indicate whether there is any objection, will NOT be required while the case is in PAR.

D. Petitioner's Supporting Documents.

³ For additional guidance on information that should be included in the petition, such as the vaccinee's full name and date of birth, please refer to Section II(3) of the Guidelines for Practice Under the National Vaccine Injury Compensation Program at <https://www.uscfc.uscourts.gov/sites/default/files/Guidelines-4.24.2020.pdf>.

⁴ PAR is intended to function only as a preliminary review with the goal of identifying missing or outstanding records that are likely to delay resolution of the case when not filed with the petition. PAR does not address whether a petition was filed in good faith or with a reasonable basis and completion of PAR does not indicate that the record of the case is fully developed. The fact that a case is activated after PAR also does not prohibit Respondent or HHS from requesting the filing of additional documents (although in most cases the obtaining of such additional materials may not be invoked as grounds for the claim's delay).

The Vaccine Act and the Vaccine Rules require, at a minimum, that the petition must be supported by all medical and related records potentially relevant to the issue of whether Petitioner is entitled to an award. The necessary records and affidavits are further described in Vaccine Rule 2(c) and the *Guidelines for Practice Under the National Vaccine Injury Compensation Program* (“*Guidelines*”).⁵ Detailed guidance regarding the filing of these documents can also be found in the *Guidelines*.

In order to complete the PAR process, Petitioner shall file certified⁶ copies of the following:

- 1. Vaccination record(s) (which includes the date and place of vaccination, see Vaccine Rule 2(c)(1)(A)(ii));⁷**
- 2. Records evidencing diagnosis of alleged vaccine related injury;**
- 3. Records of treatment prior to vaccination;⁸**
- 4. Records evidencing that the vaccine related injury persisted for at least six months or resulted in death or inpatient hospitalization and surgical intervention;**
- 5. Records evidencing vaccinee’s general health and condition both before and after the implicated vaccination(s);**
- 6. An affidavit from Petitioner addressing the requirements of § 11(c)(1), to include the lack of or disposition of any prior civil action;**

⁵ Both resources can be found on the court’s website under Vaccine Information. The link for the Vaccine Rules is <http://www.uscfc.uscourts.gov/sites/default/files/170801VaccineRules.pdf>. The link for the *Guidelines* is <http://www.cofc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>

⁶ All records required by this order must be certified as a complete and accurate set of records as kept in the normal course of business by the provider’s custodian of records. See Vaccine Rule 2(c)(2)(A) and Section E of this Order.

⁷ For cases alleging a Shoulder Injury Related to Vaccine Administration (“SIRVA”), Petitioner shall request and file a vaccination record that includes a notation identifying of the arm of administration of the vaccine(s) at issue in the case. If Petitioner is unable to obtain this information, an affidavit of unavailability detailing Petitioner’s efforts to obtain this information shall be filed.

⁸ In the case of an infant or child under the age of three at the time the vaccine was administered, the documents supporting the petition should include all medical records, including laboratory and genetic testing records, relating to the pregnancy and birth, and all records pertaining to the infant prior to the vaccination, including those of “well baby” visits. If the vaccine is an older child or an adult, the filed records should include all records from the primary care provider for three years prior to the administration of the vaccine(s) alleged to be causal.

7. PAR Questionnaire (see section G below), and

8. Statement of Completion.⁹

Depending on the facts and circumstances of the case, Petitioner may be required to provide additional affidavits or to incorporate or describe additional information in an affidavit. For example, any required records which are unavailable must be identified and the reason for their unavailability must be explained in an affidavit. § 11(c)(3); Vaccine Rule 2(c)(2)(B)(i). Furthermore, “[i]f petitioner’s claim does not rely on medical records alone but is also based in any part on the observations or testimony of any person, Petitioner should include the substance of each person’s proposed testimony in a detailed affidavit(s) supporting all elements of the allegations made in the petition.” Vaccine Rule 2(c)(2)(B)(ii).

Once the certified records and affidavit(s) have been filed, Petitioner shall file a Statement of Completion using the CM/ECF event entitled “Statement of Completion.” **The required records, affidavit(s), and Statement of Completion shall be filed as set forth in Sections A and E.**

E. Certified Records¹⁰

In order to complete the PAR process, all petitions filed on or after **Wednesday, January 1, 2020, must be filed with certified records** sufficient to satisfy Section 11(c) of the Vaccine Act from each medical provider. The records from each medical provider must be certified as complete by that provider unless documentation is included stating that the records were obtained pursuant to the Health Information Technology for Economic and Clinical Health Act (HITECH). In the rare event that a medical provider or third party record retrieval copy company will not provide the requested certification, Petitioner’s counsel shall file an affidavit pursuant to Vaccine Rule 2(c)(2)(B)(i) explaining the unavailability of certified copies of the medical records and confirming that counsel has filed a complete set of the records as provided by the medical provider to the attorney. An affidavit by counsel pursuant to Vaccine Rule 2(c)(2)(B)(i) must also be filed in the event that any relevant records are otherwise missing or unavailable. If a medical facility does not maintain a medical records certification form, a sample form can be found at <http://www.cofc.uscourts.gov/vaccine-sample-filings>.

Note: If medical records were requested prior to January 1, 2020, Petitioner will not be required to file a certification of records in order to complete the PAR review process (Petitioner shall submit the request form with the records to demonstrate that the records were requested prior to January 1, 2020). Only records requested on or after January 1, 2020, will be subject to the certification requirement.

⁹ See Vaccine Rule 2(f).

¹⁰ Vaccine Rule 2(c)(2)(A)

F. Motions for Authorization to Issue a Subpoena.

If a Petitioner requires an order for authorization to issue a subpoena, a motion requesting this authorization shall be filed as soon as possible. The motion shall state with specificity the name of the medical provider, the address, and all relevant contact information for the custodian of records.

G. PAR Medical History Questionnaire.

As of **Wednesday, January 1, 2020**, Petitioners will be required to file a completed PAR Questionnaire in order to complete the PAR process. Petitioner shall file the PAR Questionnaire as an exhibit, utilizing a Notice of Filing, and selecting the CM/ECF event entitled "PAR Questionnaire." The PAR Questionnaire is found at: http://www.cofc.uscourts.gov/sites/default/files/PAR%20Questionnaire_Fillable%20PDF.pdf.

H. PAR Completion - Activation and Reassignment Order.

Once the pre-assignment review process is complete and all necessary documentation has been filed, an Activation and Reassignment Order will be issued, certifying that PAR review is complete. The petition will thereafter be assigned either to a special master or to the SPU for further proceedings. The special master to whom the case is assigned will subsequently issue another scheduling or initial order setting forth additional information and deadlines for further proceedings.

I. Scheduling Order

The following is **ORDERED**: Petitioner shall file certified records required by Section E of this Order by the deadline set forth on page one of this Order.

Any questions regarding this order may be directed to Staff Attorney, Francina Segbefia, at (202) 357-6358, francina_segbefia@cfc.uscourts.gov.¹¹

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master

¹¹ In the event that a disruption in court operations renders the Office of Special Masters inaccessible, the parties are directed to consult the website of the United States Court of Federal Claims. Alternatively, the parties may call the Clerk's Office, at (202) 357-6366.